

Support for the amendments to claims 48 and 49 may be found in the specification under the section "**Gene Mapping and Genetic Trait Analysis Using SNPs.**" Page 42, line 19 to page 45, line 26. Specifically, the specification provides that polymorphisms "can be analyzed to determine whether the presence or absence of a particular polymorphism *correlates* with a particular trait." *See* page 42, lines 22-26. Support for the phrase "segregates non-randomly" may be found, for example, at page 43, lines 1-15.

As the Examiner has pointed out the chemical polyoxyethylenesorbitan-20 is commonly referred to by the trademark -- TWEEN-20 --. In view of the Examiner's objection and in the interests of furthering the prosecution of this application, Applicants have amended the specification to refer to the trademark TWEEN-20 by its chemical name -- polyoxyethylenesorbitan-20 --. Applicants have reviewed the entirety of the specification and it appears that all occurrences of the use of the trademark TWEEN-20 have been corrected. As such, the Examiner's objection should be withdrawn.

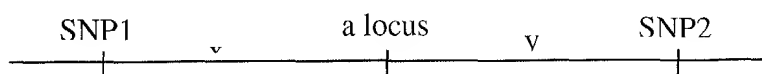
II. Rejection under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claims 34-38, 42-44, and 47-50 under 35 U.S.C. § 112, first paragraph out of a concern that these claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse the Examiner's rejection and request reconsideration.

The Examiner proffers that the specification fails to provide adequate written description support for "selecting said at least two single nucleotide polymorphic sites." However, as the Examiner will note, the specification, under the section "**Identification and Parentage Verification,**" clearly recites that SNPs genetically linked to two or more loci (i.e., two or more single nucleotide polymorphisms that segregate non-randomly with respect to such loci) can be analyzed to determine the probability that a given individual will share the same genetic trait. *See* page 28, line 10 – page 42, line 17. Further support for the phrase "selecting said at least two single nucleotide polymorphic sites" may be found at page 6, line 27 to page 7, line 16 of the specification, which describes a method of creating a genetic map of a target organism by analyzing at least two polymorphic sites and comparing the results of such analysis to a reference organism. As such, the Examiner's rejection may be properly withdrawn.

The Examiner also proffers that the specification fails to provide sufficient written description support for the phrase "said single nucleotide polymorphic sites is within about 150

bases of said genetic trait.” Applicants respectfully traverse the Examiner’s rejection and request reconsideration. As the Examiner has stated, the specification provides that “a SNP can, statistically, be found within 150 bases of any particular genetic mutation or lesion.” See page 14, lines 13-17 (emphasis added). One embodiment of the presently claimed invention is drawn to a single nucleotide polymorphism “within *about* 150 bases of said genetic trait”. As the Examiner will appreciate, the term “about” is a proper term that can be used to define ranges that have been statistically determined. By its very definition, the term “statistically” means that the single nucleotide polymorphism, on average, will be found within *about* 150 bases. The specification teaches that SNPs occur with uniform distribution, approximately 300 bp apart. As the Examiner will appreciate, any locus characteristic must therefore lie at a position flanked by SNPs:



where $x+y \approx 300$ bases. As it is therefore apparent, at least one of x or y must be \leq about 150 bases. Furthermore, Applicants assert that a person of skill in the art, at the time of the invention, would have understood from the cited passage that Applicants had possession of the presently claimed invention at the time of the invention. As such, Applicants assert that the Examiner’s rejection may be properly withdrawn.

It also appears that the Examiner is suggesting that because the SNP of interest could occur in either a coding or non-coding region such a SNP would not correlate with a “genetic trait.” However, as the Examiner will appreciate, the SNP of interest need not actually cause the “genetic trait” (i.e., occur within the coding region of the gene that causes the genetic trait). Rather, the present invention is drawn to a method for determining a genetic trait by detecting single nucleotide polymorphism(s) that is genetically linked to and that correlates with the genetic trait of interest. The single nucleotide polymorphism(s) of the present invention is genetically linked to the genetic trait because it exhibits non-random segregation. The single nucleotide polymorphism(s) of the present invention correlate with the genetic trait because the identity of the nucleotide of the single nucleotide polymorphism(s) is associated with the presence or absence of the genetic trait. As such, the polymorphism(s) can be located in non-coding regions so long as it is genetically linked to and correlate with the genetic trait of interest. Thus, the Examiner’s objection is improper and should be withdrawn.

It also appears that the Examiner is concerned about whether the specification provides adequate written description of the mutations to be analyzed, their respective flanking sequences and the SNP(s) of interest such that the skilled artisan would be able to synthesize primers that

would hybridize to a region flanking the SNP(s). Applicants respectfully traverse the Examiner's objection and request reconsideration.

The present invention is drawn to a method (for analyzing DNA) and *not* a composition of matter as in *In re Fischer*, 166 USPQ 18, 24 (CCPA 1970), upon which the Examiner has relied in support of his rejection. As such, the Examiner's reliance on *In re Fischer* is inappropriate. However, assuming *arguendo* that *In re Fischer* were applicable, Applicants assert that the specification provides adequate written description support to those of skill in the art, at the time of the invention, how to determine SNPs and their respective flanking sequences. Such methods are described, for example, in the section "**Methods for Discovering Novel Polymorphic Sites.**" See page 16, line 25 to page 19, line 7. Applicants respectfully submit that a person of skill in the art can practice the present invention without undue experimentation. The methods needed to practice the claimed invention are well known to those of skill in the art and are routinely performed in a manner consistent with the present invention. Therefore, the Examiner's rejection is improper and should be withdrawn.

Although the Examiner has stated that the specification presents guidance for the analysis of equine sequences, the Examiner proffers that the specification fails to provide sufficient guidance with regard to the testing and evaluation of human sequences (citing *Genentech Inc. v. Novo Nordisk A/S*, 42 USPQ2d 1001 (Fed. Cir. 1997)). However, as the Examiner will note, the specification clearly recites that "[h]uman single nucleotide polymorphisms may be used in the same manner as ... equine polymorphisms," and provides detailed examples of the analysis of equine and human sequences. See page 58, lines 6-7. The specification goes on to recite that

The invention is illustrated below with respect to two of its embodiments – horses and humans. However, because the fundamental tenets of genetics apply irrespective of species, such illustration is equally applicable to any other species. Those of ordinary skill would therefore need only to employ the methods of the above invention to isolate SNPs in any other species, and to thereby conduct the genetic analysis of the present invention. (Page 44, lines 29-36).

As such, the Examiner's citation of *Genentech Inc. v. Novo Nordisk A/S*, 42 USPQ2d 1001 (Fed. Cir. 1997) is inappropriate. The specification teaches one of skill in the art sufficient guidance with regard to the testing and evaluation of equine and **human** sequences. Therefore, the Examiner's rejection is improper and should be withdrawn.

The Examiner has objected to claims 49 and 50 as lacking adequate support within the specification for "conditions sufficient to permit a polymerase mediated, template-dependent

[primer] extension" reaction. However, as the Examiner will note, the specification provides literal antecedent support for this phrase. *See*, for example, page 5, lines 22-25. Additional support of both the literal conditions and those conditions known by those of skill in the art are described in the specification at, for example, Section I.A. ("**The Attributes Of The Polymorphisms**" from page 10, line 9 to page 13, line 18), as well as in Examples 1-6. Assuming *arguendo* that the specification does not describe "conditions sufficient to permit a polymerase mediated, template-dependent [primer] extension" reaction, such conditions are well known to those of skill in the art. As the Examiner will appreciate, it is well established that "a patent need not teach, and preferably omits, what is well known in the art. *See Hybridtech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986). Therefore, the Examiner's objection is improper and should be withdrawn.


III. Rejection under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 34-38, 42-44, and 47-48 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as their invention. Specifically, the Examiner has objected to the use of the phrase "a reference organism" in claim 47 as being indefinite. The Examiner has objected to claims 34-38, 42-44 and 48 because these claims depend upon claim 47. Applicants respectfully submit that the amendment to claim 47 obviates the Examiner's objection. As such, the Examiner's objection should be withdrawn with respect to claims 34-38, 42-44, and 47-48.

Applicants submit that the present response fully addresses all of the Examiner's objections and concerns. Applicants further submit that the application, as amended, is in condition for allowance and earnestly solicit early notification of such favorable action.

Respectfully submitted,

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